PRV

PATENT- OCH REGISTRERINGSVERKET
Patentavdelningen

SE00/01278

4

Intyg
C rtificate

Härmed intygas att bifogade kopior överensstämmer med de handlingar som ursprungligen ingivits till Patent- och registreringsverket i nedannämnda ansökan.

This is to certify that the annexed is a true copy of the documents as originally filed with the Patent- and Registration Office in connection with the following patent application.

(71) *Sökande* / *Applicant (s)* — *SHL Medical AB, Nacka SE*

(21) *Patentansökningsnummer* / *Patent application number* — *9903663-4*

(86) *Ingivningsdatum* / *Date of filing* — *1999-10-12*

Stockholm, 2000-08-14

För Patent- och registreringsverket
For the Patent- and Registration Office

A. Södervall
Anita Södervall

Avgift
Fee

PRIORITY DOCUMENT
SUBMITTED OR TRANSMITTED IN COMPLIANCE WITH RULE 17.1(a) OR (b)

BEST AVAILABLE COPY

PATENT- OCH REGISTRERINGSVERKET
SWEDEN

Postadress/Adress
Box 5055
S-102 42 STOCKHOLM

Telefon/Phone
+46 8 782 25 00
Vx 08-782 25 00

Telex
17978
PATOREG S

Telefax
+46 8 666 02 86
08-666 02 86

INHALER SAFETY DEVICE

TECHNICAL FIELD

The present invention relates to a device for an inhaler, which inhaler comprises an air passage inside the inhaler, an opening intended for inhalation of medicament in fluid connection with said air passage, means for delivering a dose of medicament into said air passage, means for activating said dose delivering means, wherein said activating means is activated by an air flow through said air passage.

BACKGROUND OF THE INVENTION

Inhalers for inhaling medicament into the respiratory tract comprise some sort of opening, typically also with a mouthpiece, and an air flow passage inside the inhaler in communication with the opening. A compartment containing medicament and dose delivering means are also arranged and in communication with the air passage so that, when the patient inhales, air and medicament will mix in the air passage and will be inhaled by the patient.

A plurality of inhalers present on the market are provided with breath activated dose delivering means, so called breath activated inhalers. These function so as to deliver a dose of medicament when the patient inhales, i e when there is an air flow present in the air passage. In contrast to inhalers where the patient physically has to activate the dose delivering means, e g by pressing parts of the inhaler, manoeuvring levers and the like, the breath activated inhalers are triggered by the inhalation. This provides a more reliable dose delivery to the patient because the patient no longer has to time the inhalation with physical activation of the inhaler.

A drawback with these breath activated inhalers is unintentional or accidental activation of the inhaler, especially by children. A child

often registers the activities of the adults and tries to do the same thing as them. If for example a parent uses an inhaler to inhale medicament, it is very likely that the child finds that interesting and would like to do the same. If the inhaler is then left within the child's reach it is likely that it would try to inhale. The inhaler would then be triggered to deliver a dose of medicament which the child unintentionally could inhale. Since these medicaments sometimes are quite potent, or even lethal, there is a risk that the child will suffer from poisoning which could lead to serious consequences.

BRIEF DESCRIPTION OF THE INVENTION

The aim of the present invention is to avoid the above mentioned problems concerning unintentional/accidental activation of breath activated inhalers.

This aim is obtained by a device for a breath activated inhaler where the device comprises user operated safety means arranged and positioned such that it prevents activation of said activating means when the safety means is in a non-operated state.

According to one aspect of the invention it is characterised in that said safety device comprises an auxiliary air passage in communication with the inhalation air passage and in communication with the outside of the inhaler via at least one opening, and user operated means for blocking said auxiliary air passage when an inhalation of medicament is to be performed.

According to yet an aspect of the invention it is characterised in that the user operated means comprises parts of a hand of a user of the inhaler.

According to a further aspect of the invention, it is characterised in that there are at least two openings and that they are arranged such on the inhaler that they cannot be reached by the fingers of a child's one hand. Further the openings may be arranged such on the inhaler that they cannot be reached by the fingers of an adults one hand and/or that the size of the opening is such that a finger of a child cannot block the opening.

The advantage of the invention over prior art is that when the safety means is not operated, any unintentional inhalation through the inhaler will not affect the activating means. Since the activating means is triggered by the air flow through the inhaler during inhalation, a manipulation of this air flow preventing the activating means to be unintentionally activated provides an easy and reliable safety device.

The blocking of the auxiliary air passage may be obtained in many different ways, for example by the finger or hand of the user, by flaps or lids or the like.

Preferably, the openings are arranged such on the inhaler, and/or have such sizes, that only an adult is able of blocking the openings in order to activate the activating means upon inhalation.

It is to be noted that the present invention may be used with all breath activated or breath controlled inhalers, regardless of type of medicament.

These and other aspects of, and advantages with, the present invention will become apparent from the following detailed description of illustrative embodiments and from the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

In the detailed description of the invention, reference will be made to the accompanying drawings, of which:

Fig. 1 shows a side view in cross-section of an inhaler for aerosol-driven medicament with a device according to the invention, and

Fig. 2 shows a part view in cross-section of an inhaler for powder medicament with a device according to the invention.

DETAILED DESCRIPTION OF THE INVENTION

Fig. 1 shows, as an example, an inhaler for aerosol-driven medicament which may utilise the present invention. The inhaler comprises a housing 10 with an opening 12 intended for inhalation of a dose of medicament. Inside the housing is arranged a canister 14 containing the medicament and aerosol as propellant. The canister is provided with dose delivery mechanism comprising a spring-loaded stem 16. The stem is provided with a passage extending into the canister. The stem/lower part of the canister is supported by a holding/fixating device 18.

At the opposite end of the canister stem, an activating means 20 is arranged. It comprises in the embodiment shown a spring 22 with one end pressing on the canister and the other end supported by a holder 24.

The activating means further comprises an air inlet 26 arranged in the inhaler housing and a flap 28 pivotally arranged adjacent the air intake. When the flap is in a resting, inactivated, position, it covers the air intake. Arranged in contact with the flap is a holding means 30, which in the embodiment shown comprises an elongated arm

extending alongside the canister side. The arm is at its lower end arranged with a ledge 32. When in a resting position, the arm and the ledge holds the canister in an inactivated position against the force of the spring. The interior of the inhaler, from the inhalation opening to the air intake forms an air passage.

The inhaler further comprises a safety means. It comprises at least one auxiliary air intake 34 arranged to communicate with the inhaler air passage, forming an auxiliary air passage with the inhalation opening, where the intake is positioned between the inhalation opening and the flap/main air intake. Further auxiliary air intakes 36 are shown with broken lines.

In normal use of the inhaler, without the safety means, the start of an inhalation through the inhalation opening causes a pressure difference between the interior and the exterior of the inhaler. This pressure difference causes the flap to pivot, thereby causing an air flow through the inhaler from the air intake to the inhalation opening. The pivoting movement of the flap acts on the elongated arm so that the arm is swung away somewhat from the canister. This causes the ledge to release the canister from its inactivated position. The force of the spring causes the canister to depress whereby the stem is pressed into the canister and a dose is delivered to the inhalation opening, which dose is inhaled by the patient.

When the safety device according to the invention is used with the inhaler and the auxiliary air intake is closed, the function is as described above.

If on the other hand someone tries to inhale without closing the auxiliary air intake, an air flow passage is created from the auxiliary air intake to the inhalation opening, thereby preventing a build-up of

a pressure difference inside the inhaler. Because no pressure difference is created, the flap will not be affected by the inhalation.

Fig. 2 shows another example of an inhaler where the present invention is utilised. The inhaler shown is intended for medicament in powder form. The inhaler comprises a housing 40. At one end of the housing a mouthpiece 42 with an inhalation opening 44 is arranged. The mouthpiece can be protected by a protective cover 46.

Arranged inside the opening is a means for enabling access to medicament. The means comprises an elongated body 48 with a passage through its length, hereafter named outlet passage. One end 50, the one facing inwards, is arranged with sharpened edges. The elongated body is slidably supported in a hole in the opening, whereby the other end of the elongated body is arranged in the opening. An activating means is arranged to the elongated body, comprising an air intake 52, a flap 54 pivotally arranged adjacent the air intake and a mechanism 56 designed to be able of moving the elongated body inwards when the flap is opened.

Further inside the inhaler and the elongated body a wheel 58 is rotatably arranged. The wheel is arranged with a plurality of recesses 60 and means for rotating the wheel to different positions.

The medicament is packaged in blisters, where each blister enclosure contains one dose of medicament. The blister enclosures are placed in the recesses.

The inhaler further comprises a safety means. It comprises at least one auxiliary air intake 80 arranged to communicate with the inhaler interior, forming an auxiliary air passage with the inhalation opening.

During normal use, without the device according to the invention, the inhalation causes a pressure difference between the interior and the exterior of the inhaler. This pressure difference causes the flap 54 to open and an air flow to be created through the air intake 52 and the passage of the elongated body 48. The movement of the flap causes the activating means to move the elongated body forward so that its pointed end penetrates the blister enclosure whereby a passage between the interior of the enclosure and the inhalation opening is created so that medicament is inhaled.

When the safety device according to the invention is used with the inhaler and the auxiliary air intake 80 is closed, the function is as described above.

If on the other hand someone tries to inhale without closing the auxiliary air intake, an air flow passage is created from the auxiliary air intake 80 through passage of the elongated body to the inhalation opening, thereby preventing a build-up of a pressure difference inside the inhaler. Because no pressure difference is created, the flap will not be affected by the inhalation.

In this context it is to be understood that the auxiliary air intake may be closed or blocked by the fingers of the patient or by a mechanical means. Since the greatest risk of unintentional inhalation is from children, the air intakes should preferably be placed so that a child cannot close the auxiliary intake without great effort.

There a several ways of obtaining this. One way is that the size of the auxiliary air intake is such that a child's finger cannot block it. Another way is that there are several auxiliary air intakes arranged in the inhaler housing so that it is difficult for a child to place several fingers over all of the intakes. Further the distance between the

intakes could be such that it is impossible for a child's hand to reach all the intakes.

If the medicament is of a very potent, toxic, or even lethal kind, if inhaled wrongly, the device could be designed such, and with the auxiliary air intakes positioned such that both hands are needed in order to cover or block all intakes.

In this context it is to be noted that, if more than one auxiliary air intake is used, the activating means is arranged such that it is only activated when a pressure drop corresponding to a complete blocking of all intakes is reached, i e it shall not be sufficient to block some of the auxiliary air intakes in order to activate the inhaler. By providing different number of openings and by arranging these with different configurations, different "levels of security" may be obtained with the present invention.

PATENT CLAIMS

1. Device for an inhaler, which inhaler comprises an air passage inside the inhaler, an opening (12, 44) intended for inhalation of medicament in fluid connection with said air passage, means for delivering a dose of medicament (14, 16, 22, 48, 50, 60) into said air passage, means for activating said dose delivering means (26, 28 30, 52, 54, 56), wherein said activating means is activated by an air flow through said air passage, c h a r a c t e r i s e d in that the device comprises user operated safety means (34, 80) arranged and positioned such that it prevents activation of said activating means when the safety means is in a non-operated state.

2. Device according to claim 1, c h a r a c t e r i s e d in that said safety device comprises an auxiliary air passage in communication with the inhalation air passage and in communication with the outside of the inhaler via at least one opening, and user operated means for blocking said auxiliary air passage when an inhalation of medicament is to be performed.

3. Device according to claim 2, c h a r a c t e r i s e d in that the user operated means comprises parts of a hand of a user of the inhaler.

4. Device according to claim 3, c h a r a c t e r i s e d in that there are at least two openings and that they are arranged such on the inhaler that they cannot be reached by the fingers of a child's one hand.

5. Device according to claim 3, c h a r a c t e r i s e d in that there are at least two openings and that they are arranged such on the inhaler that they cannot be reached by the fingers of an adults one hand.

6. Device according to claim 3, c h a r a c t e r i s e d in that the size of the opening is such that a finger of a child cannot block the opening.

ABSTRACT

The present invention relates to a device for an inhaler, which inhaler comprises an air passage inside the inhaler, an opening (12, 44) intended for inhalation of medicament in fluid connection with said air passage, means for delivering a dose of medicament (14, 16, 22, 48, 50, 60) into said air passage, means for activating said dose delivering means (26, 28 30, 52, 54, 56), wherein said activating means is activated by an air flow through said air passage. The device is characterised in that the device comprises user operated safety means (34, 80) arranged and positioned such that it prevents activation of said activating means when the safety means is in a non-operated state.

(Fig. 1)

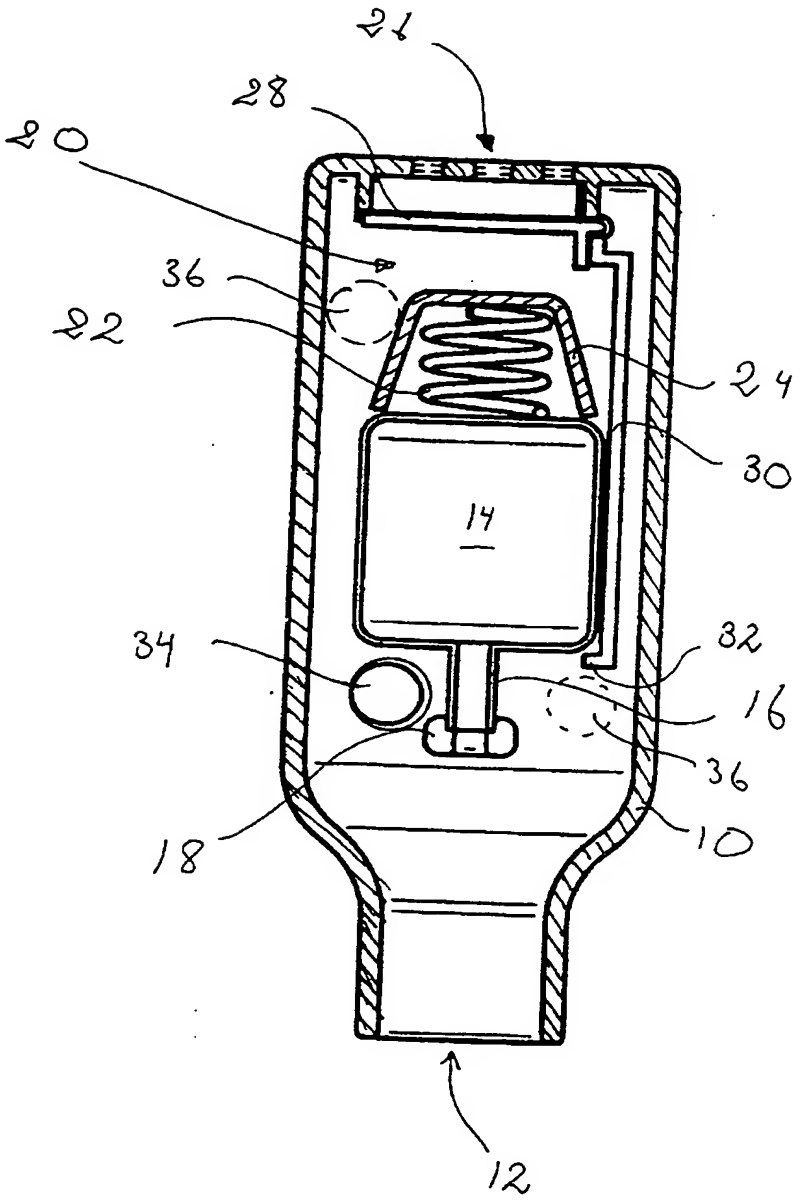

Fig. 1

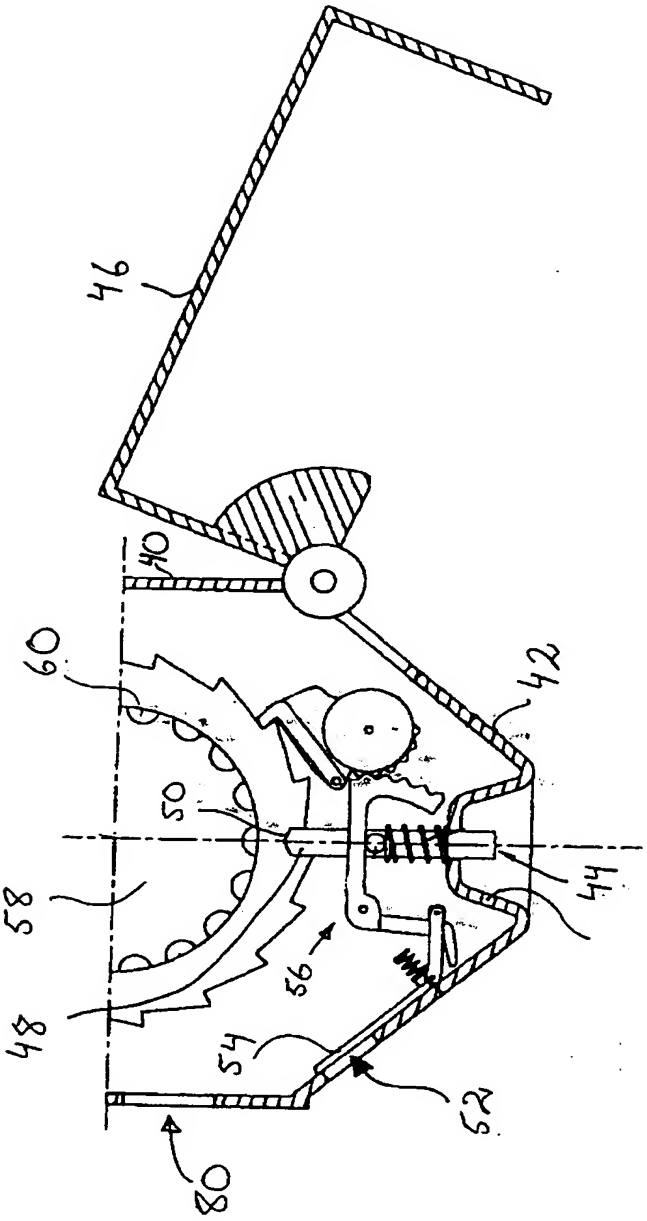

Fig. 2